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Docket No.: 025444.1132-US01  
(PATENT)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of:  
Melton B. Affrime et al.

Application No.: 09/760,588-Conf. #4299

Group Art Unit: 1614

Filed: January 16, 2001

Examiner: D. A. Jagoe

For: TREATING ALLERGIC AND  
INFLAMMATORY CONDITIONS

**TRANSMITTAL LETTER**

**MS Appeal Brief - Patents**  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Dear Sir:

Enclosed are the following items for filing in connection with the above-referenced Patent Application:

1. Reply Brief; and
2. Return receipt postcard.

The Director is hereby authorized to charge any deficiency in the fees filed, asserted to be filed or which should have been filed herewith (or with any paper hereafter filed in this application by this firm) to our Deposit Account No. 50-0740, under Order No. 025444.1132-US01. A duplicate copy of this paper is enclosed.

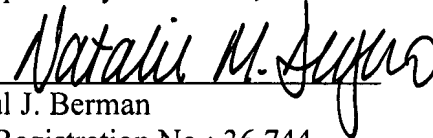
It is not believed that extensions of time or fees for net addition of claims are required beyond those that may otherwise be provided for in documents accompanying this paper. However, if additional extensions of time are necessary to prevent abandonment of this application, then such extensions of time are hereby petitioned under 37 C.F.R. § 1.136(b), and

any fees required therefor (including fees for net addition of claims) are hereby authorized to be charged to our Deposit Account No. 50-0740.

Dated: May 7, 2007

Respectfully submitted,

By

  
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**REPLY BRIEF**

**MS Appeal Brief - Patents**  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Dear Sir:

**INTRODUCTION**

Applicants are filing this Reply Brief as a matter of right, pursuant to 37 C.F.R. §§ 41.41(a)(1), within two months from the mailing date of the Examiner's Answer, which is dated March 8, 2007. No fees are believed to be required for submission of this Appeal Brief. However, if additional fees or extensions of time are necessary to prevent abandonment of this application, then such extensions of time are hereby petitioned under 37 C.F.R. § 1.136(b), and any fees required therefor (including additional fees required for this appeal) are hereby authorized to be charged to our Deposit Account No. 50-0740.

ARGUMENT

The Examiner's Answer, like prior Office Actions, persists in applying an incorrect legal standard for inherent anticipation to Applicants' claimed invention. The proper test for inherent anticipation is whether the claimed invention "necessarily results from" the disclosure in the allegedly inherently anticipating reference, namely, U.S. Patent No. 6,100,274 to Kou ("Kou patent"). (*See, e.g., Nicholas v. Perricone, M.D. v. Medicis Pharmaceutical Corporation*, 432 F.3d 1368, 1376-1380 (Fed. Cir. 2005); *Schering Corp. v. Geneva Pharmaceuticals, Inc.*, 339 F.3d 1373, 1381 (Fed. Cir. 2003); and *Rapoport v. Dement*, 254 F.3d 1053, 1062-63 (Fed. Cir. 2001).) As the Federal Circuit confirmed in *Continental Can Co. v. Monsanto Co.*, 948 F.2d 1264, 1269 (Fed. Cir. 1991), "[i]nherency ... may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient."

The Examiner still has not asserted that the claimed invention necessarily results from the Kou patent. Instead the Examiner continues to assert that one of ordinary skill in the art "is able to readily envisage" the claimed invention. Examiner's Answer, page 5. This, however, is not the correct legal standard, and is far from a finding that the claimed invention necessarily results from the Kou patent.

Applicants submit that the Examiner has not presented evidence or reasoning "tending to show inherency." The very "evidence or reasoning" that the Examiner presents undercuts the assertion that the claimed invention is anticipated. The Examiner quotes from the Kou patent that, "the course of precise dosage and dosage regimen may be varied depending on the requirements of the patients as well as the severity of the

allergic condition being treated and the determination of a proper dosage and dosage regimen for a particular patient will be within the skill of the attending physician.”

Examiner’s Answer, page 7, citing the Kou patent, column 5, lines 43-54. The Examiner acknowledges that a physician would make a determination as to the length of treatment, thereby recognizing the possibility, indeed probability, that the disclosure in the Kou patent may lead to many different dosage regimes of different durations and different amounts of administered desloratadine. Applicants note that the Examiner does not state that each of the various dosages and dosage regimens within the skill of the attending physician would necessarily result in a steady state plasma level of desloratadine that is a requirement of every claim.

According to MPEP ¶ 1207.02(A)(9)(e), when as here there are questions regarding how claim limitations correspond to features of the prior art in the context of a rejection pursuant to §102, the Examiner’s Answer must include a side-by-side comparison of the claim language with the allegedly anticipating disclosure. Applicants submit that a side-by-side comparison would show, as we have maintained throughout this prosecution, that the Kou patent does not necessarily result in each and every feature of the claimed invention.

The U.S. Patent and Trademark Office must examine patent applications in accordance with the law, as established by the courts, including the Federal Circuit. Indeed, the correct standard for inherent anticipation is reflected in the Manual of Patent Examining Procedure: “To establish inherency, the extrinsic evidence must ‘make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill. Inherency,

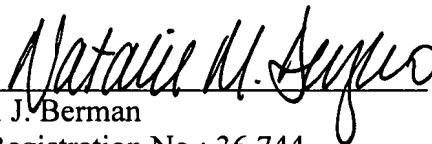
however, may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient.” MPEP ¶ 2112, part IV (Rev. 5, August 2006) at 2100-47, *quoting In re Robertson*, 169 F.3d 743, 745, 49 USPQ2d 1949, 1950-51 (Fed. Cir. 1999). The Examiner’s Answer does not assert that the claimed invention necessarily results from the Kou patent. The Examiner’s arguments that the claimed invention is possible or even probable from practicing the Kou patent are, in the words of the Federal Circuit and the MPEP, not sufficient.

### CONCLUSION

Applicants respectfully urge the Board to find that the invention of claims 69-84 is not anticipated by the Kou patent and, therefore, that the rejection of those claims pursuant to 35 U.S.C. § 102(e) is improper, and should be withdrawn.

Dated: May 7, 2007

Respectfully submitted,

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